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09/763,982

04/25/2001

Scott L. Diamond

PENN0754

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10/31/2002

LICATLA & TYRRELL P.C.

66 E. MAIN STREET

MARLTON, NJ 08053

EXAMINER

SCHNIZER, RICHARD A

ART UNIT

PAPER NUMBER

1635

DATE MAILED: 10/31/2002

12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/763,982

Applicant(s)
Diamond et al

Examiner
Richard Schnizer

Art Unit
1635



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Aug 22, 2002
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 8 is/are allowed.
- 6) ☒ Claim(s) 1-7 and 9-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

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DETAILED ACTION

An amendment was received and entered as Paper No.11 on 8/22/02.

Claim 14 was canceled as requested. Claims 1-13 remain pending and are under consideration in this Office Action.

Claim Objections

Applicant's amendment overcomes the objection to Claim 1.

Rejections Withdrawn

Applicant's amendments overcome the rejections under 35 USC 112, second paragraph.

After further consideration, the rejection of claims 1-7 and 9-13 under 35 USC 102(b) over Jans et al is withdrawn.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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Claims 1-7 and 9-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Thatcher et al (WO 96/41606, published 12/27/99) for the reasons of record in Paper No. 10.

Thatcher teaches a composition comprising a cationic peptide scaffold (NBC2; see page 8, line 20), the nuclear localization targeting peptide encoded by SEQ ID NO:3 of the instant invention (M9, comprising the NLS of hnRNP A1, see page 92, lines 3-6), wherein the scaffold and the targeting peptide are conjugated by a hydrolytic-resistant linkage (see page 92, last full paragraph). The composition is useful in methods of transferring DNA to nuclei of cells and subsequently expressing encoded genes. See for example page 91, first paragraph. See also abstract; first page of summary; page 5, lines 8, 9, 20, 21, page 10, lines 7-9; page 20, lines 2-7; page 26, lines 16-20; page 32, lines 3-8; page 92, lines 1-4; and claim 22 on page 121.

Response to Arguments

Applicant's arguments filed 8/22/02 have been fully considered but they are not persuasive.

Applicant argues in the paragraph bridging pages 7 and 8 of the response that Thatcher fails to anticipate the invention because the composition of Thatcher comprises a classical nuclear localization signal in addition to a non-classical nuclear localization signal (NLS). This is unpersuasive because, while the claims require a non-classical NLS, they do not exclude the presence of a classical NLS. So a composition comprising both classical and non-classical NLSs anticipates the claims.

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Applicant argues in the paragraph bridging pages 8 and 9 of the response that Thatcher does not teach compositions for the transfer of DNA to the nuclei of cells, stating that no such experiments were performed. This is unpersuasive because Thatcher discloses a composition with the physical characteristics of the claimed invention. The function is inherent in the structure. The office does not have the facilities for examining and comparing applicant's product with the product of the prior art in order to establish that the product of the prior art does not possess the same material, structural and functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is upon the applicant to prove that the claimed products are functionally different than those taught by the prior art and to establish patentable differences. See Ex parte Phillips, 28 USPQ 1302, 1303 (BPAI 1993), In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and Ex parte Gray, 10 USPQ2d 1922, 1923 (BPAI 1989). "When the structure recited in the reference is substantially identical to that of the claims, claimed properties or functions are presumed to be inherent." See MPEP 2112.01 or In re Best, 195 USPQ 430, 433 (CCPA 1997). Applicant questions the operability of the composition of Thatcher stating that it is known that M9 forms dimers under the conditions taught by Thatcher. This is unpersuasive because it is unsupported by evidence. Applicant asserts that classical NLSs such as SV40 T antigen have not been able to get plasmid across the nuclear pore of intact cells, relying for support on the specification at page 5, lines 20-26. The specification fails to support this assertion. In fact, the specification states that such NLSs have not achieved "fully efficient gene

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transfer with 100% transfection", thereby leaving one of ordinary skill in the art the impression that transfection *was* achieved at some level less than 100%.

Conclusion

Claim 8 is allowable.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

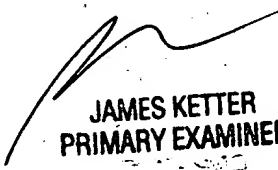
Any inquiry concerning this communication or earlier communications from the examiner(s) should be directed to Richard Schnizer, whose telephone number is 703-306-5441. The examiner can normally be reached Monday through Friday between the hours of 6:20 AM and 3:50 PM. The examiner is off on alternate Fridays, but is sometimes in the office anyway.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John Leguyader, can be reached at 703-308-0447. The FAX numbers for art unit 1632 are 703-308-4242, and 703-305-3014. Additionally correspondence can be transmitted to the following RIGHTFAX numbers: 703-872-9306 for correspondence before final rejection, and 703-872-9307 for correspondence after final rejection.

Inquiries of a general nature or relating to the status of the application should be directed to the Patent Analyst Trina Turner whose telephone number is 703-305-3413.

Richard Schnizer, Ph.D.



JAMES KETTER
PRIMARY EXAMINER